

U.S. Ser. No. 09/143,503
U.S. Control No. 90/004,946

Exhibit 43

ADVANCED CARDIOVASCULAR SYSTEMS
EXTRUSION DATA SHEET

START TIME: EXTRUSION #: 10-595-1 AMOUNT (FEET): 1000
FINISH TIME: DATE: 6/8/94 SIGNATURE/DATE John 6-8-94

MATERIALS :	MATERIAL DESC.	LOT# :	RM#
PEEK			

EXTRUDER 10 PROCESS PERSON T.T9MAS

REQUESTOR S.S.

PRODUCT 1315 SA#

SET-UP PARAMETERS:

MANREL LGTH (EXT ONLY)	FLUSH	EXPERIMENTAL Y
DIE I.D. .199	OVAL N	PRODUCTION N
MANREL O.D. .166	XHEAD Y	STRAIGHT N
SCREW TYPE <u>PE-H770-3</u>		
SCREEN TYPE 20 80 20		
START ID/OD .032/.038		
FINISH ID/OD .032/.038		

PROCESS PARAMETERS

TEMPERATURE SETPOINTS	SPEEDS & SETPOINTS	PSI & AIR
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ZONE 1 565.0 MELT <u>844</u>	SCREW RPM 2.0	HEAD PSI 792.0
ZONE 2 650.0 DIE 1 32.0	PSI SET 1259.0	DIE PSI 1259.0
ZONE 3 715.0 DIE 2 0.0	EXTR. AMP 9.1	AIR PSI 1 0.2
CLAMP 715.0 DIE 3 715.0	PUL SPEED .58	2 1.0
INLET 715.0 W/B TEMP 0.0	W/B DIST. 1INCH	3 0.3
G/PUMP 0.0		4 0.3
PMP OUT 565.0		
XHEAD 0.0		

MATERIAL DRYING TMP. 300°F DEWPOINT -54 # OF HRS DRYING 36

ACTUAL PARAMETER COLLECTED EVERY 10 MINUTES

SETPOINT	ACTUAL 1	ACTUAL 2	ACTUAL 3	ACTUAL 4	ACTUAL 5
G/PUMP PSI	1270	1242			
PUMP AMP	0	0			
SCREW RPM	2	2			
EXTRUDER AMP	11	9			
PULLER SPEED					
BARREL 1	813	785			
BARREL 2	0	0			
BARREL 3	0	0			
HEAD PSI	1270	1242			
TUBING O.D.	0.0000	0.0000			
AVG.DIA.	0.0000	0.0000			
AVG.STD.DEV.	0.0000	0.0000			

ADVANCED CARDIOVASCULAR SYSTEMS
EXTRUSION DATA SHEET

START TIME: EXTRUSION #: 10-597-1 AMOUNT (FEET): 1000
FINISH TIME: DATE: 6/8/94 SIGNATURE/DATE MM 6-8-94

MATERIALS :	MATERIAL DESC.	LOT# :	RM#
PEEK			

EXTRUDER 10 PROCESS PERSON T.T9MAS

REQUESTOR S.S.

PRODUCT 1315 SA#

SET-UP PARAMETERS:

MANDREL LGTH (EXT ONLY)	FLUSH	EXPERIMENTAL Y
DIE I.D. .199	OVAL N	PRODUCTION N
MANDREL O.D. .166	XHEAD Y	STRAIGHT N
SCREW TYPE PE 4770-3		
SCREEN TYPE 20 80 20		
START ID/OD .032/.038		
FINISH ID/OD .032/.038		

PROCESS PARAMETERS

TEMPERATURE SETPOINTS	SPEEDS & SETPOINTS	PSI & AIR
ZONE 1 565.0 MELT	SCREW RPM 2.1	HEAD PSI 733.0
ZONE 2 680.0 DIE	32.0 PSI SET 1184.0	DIE PSI 1185.0
ZONE 3 675.0 DIE	0.0 EXTR. AMP 7.4	AIR PSI 1 0.2
CLAMP 675.0 DIE	675.0 PUL SPEED .58	2 0.7
INLET 675.0 W/B TEMP	0.0 W/B DIST. 60 IN	3 0.3
G/PUMP 0.0		4 0.3
PMP OUT 565.0		
XHEAD 0.0		
MATERIAL DRYING TMP. <u>300°F</u>	DEWPOINT <u>-61</u>	# OF HRS DRYING <u>36</u>

ACTUAL PARAMETER COLLECTED EVERY 10 MINUTES

SETPOINT	ACTUAL 1	ACTUAL 2	ACTUAL 3	ACTUAL 4	ACTUAL 5
G/PUMP PSI					
PUMP AMP					
SCREW RPM					
EXTRUDER AMP					
PULLER SPEED					
BARREL 1					
BARREL 2					
BARREL 3					
HEAD PSI					
TUBING O.D.					
AVG.DIA.					
AVG.STD.DEV.					

Advanced Cardiovascular Systems

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R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
- (See R&D Production Control to Schedule Requests)

Date : 6/8/94

Requester : Steve Scheible Ext. # : 53948
 Work Home : Extrusion Dept. # : 1634
 Project : Next .014 Product : Prok shaft DOE
 Project # : 1315

Reference Document No. (SA, WC, or R)

: 100 Material : Victek PEEK 3816 Mfg or ACS # : 1 ACS or Mfg lot # : 1

Quantity : 1 Reel(s) with 1000 Feet each.

or 1 Cut Pieces 100 Cm. 100 mm

Retention time : 1 Month {Specs to be added to each end for header}

Tooling (if known) : Die : .199 to be designed
 Y or N

Mandrel : .166 Y or N

Screw : PE 4770-3 Y or N

Dimensions (as in all tool prints) : % Conc. : 100
 Special Instructions : Screw speed = 2.0 rpm

Air gap = 60"

Die Temp = 715°F

Please Illustrate Tubing Dimensions Below
 (Circle Appropriate Letter and Fill in All that Apply)

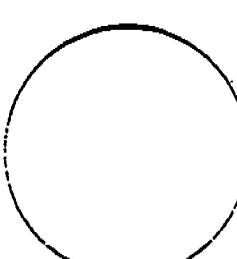
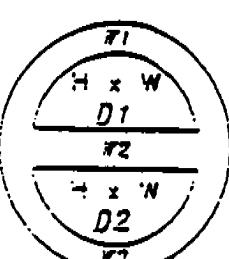
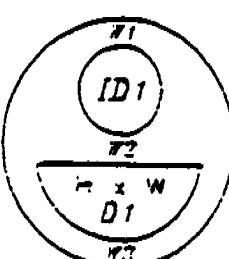
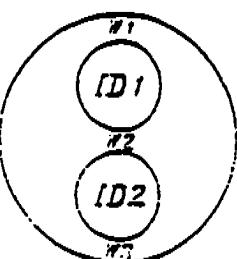
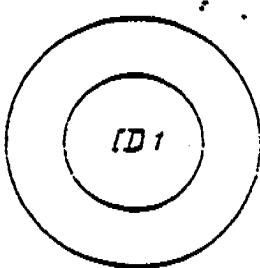
(A)

(B)

(C)

(D)

(E) (outer)



OD-X .038 +/- .001

height 1 +/- 0

= D1 1 +/- 0

OD-Y .038 +/- .001

height 1 +/- 0

= D1 1 +/- 0

ID1 .032 +/- .001

height 1 +/- 0

= D2 1 +/- 0

ID2 1 +/- 0

height 1 +/- 0

= D3 1 +/- 0

ADVANCED CARDIOVASCULAR SYSTEMS
EXTRUSION DATA SHEET

START TIME: EXTRUSION #: 10-596-1 AMOUNT (FEET): 1000
FINISH TIME: DATE: 6/8/94 SIGNATURE/DATE MM 6-8-94

MATERIALS : MATERIAL DESC. LOT# : RM#

PEEK

EXTRUDER 10 PROCESS PERSON T.T9MAS

REQUESTOR S.S.

PRODUCT 1315 SA#

SET-UP PARAMETERS:

MANDREL LGTH (EXT ONLY)	FLUSH	EXPERIMENTAL Y
DIE I.D. .199	OVAL N	PRODUCTION N
MANDREL O.D. .166	XHEAD Y	STRAIGHT N
SCREW TYPE <u>PE H70-3</u>		
SCREEN TYPE 20 80 20		
START ID/OD .032/.038		
FINISH ID/OD .032/.038		

PROCESS PARAMETERS

TEMPERATURE SETPOINTS SPEEDS & SETPOINTS PSI & AIR

ZONE 1 <u>565.0</u> MELT	<u>644</u> 0.0	SCREW RPM 2.0	HEAD PSI 752.0
ZONE 2 <u>650.0</u> DIE	1 32.0	PSI SET 1219.0	DIE PSI 1210.0
ZONE 3 715.0 DIE	2 0.0	EXTR. AMP 9.4	AIR PSI 1 0.3
CLAMP 715.0 DIE	3 715.0	PUL SPEED .58	2 0.7
INLET 715.0 W/B TEMP	0.0	W/B DIST. 60 IN	3 0.3
G/PUMP 0.0			4 0.3
PMP OUT <u>555.0</u>			
XHEAD 0.0			
MATERIAL DRYING TMP. <u>300F</u>	DEWPOINT <u>-51</u>	# OF HRS DRYING <u>36</u>	

ACTUAL PARAMETER COLLECTED EVERY 10 MINUTES

SETPOINT ACTUAL 1 ACTUAL 2 ACTUAL 3 ACTUAL 4 ACTUAL 5

G/PUMP PSI
PUMP AMP
SCREW RPM
EXTRUDER AMP
PULLER SPEED
BARREL 1
BARREL 2
BARREL 3
HEAD PSI
TUBING O.D.
AVG.DIA.
AVG.STD.DEV.

Advanced Cardiovascular Systems

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R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
- (See R&D Production Control to Schedule Requests)

Requester : Steve Scheible Ext.# : 53948

Impl. Name : Extrusion Dept.# : 1434

Project : Neet .014 Product : Prok shaft Doe
Project # : 1315

Date : 6/8/94

Reference Document Previous Extr. #

% : Material : MFG or ACS #W1 ACS or MFG lot # 1

100 Victrex PEEK 381G

Quantity : 1 Reel(s) with 1000 Feet each.

or 1 Cut Pieces 1000 mm 1000 mm

Rotation Holes : 1 M10x1.25 mm to each end for header

Leading (if known) : Die : .199 Y or N

Mandrel : .166 Y or N

Screw : PE 4770-3 Y or N

Dimensions (in mm) : % Conc. : 0.01

Special Instructions : Screw speed = 2.0 rpm

Air gap = 1.0"

Die Temp = 775 °F

Please Illustrate Tubing Dimensions Below
(Circle Appropriate Letter and Fill in All that Apply)

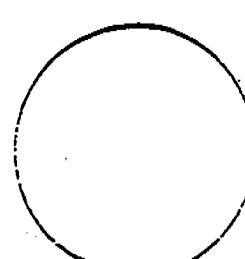
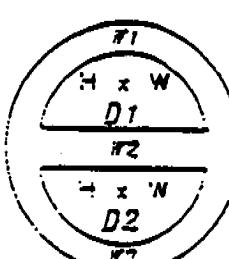
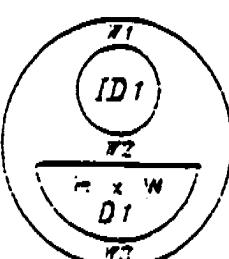
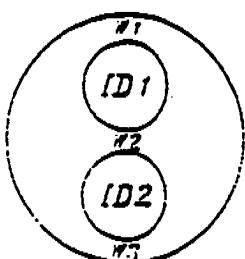
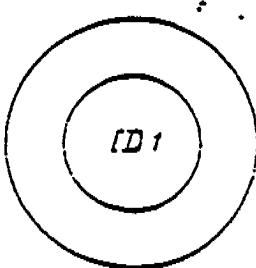
(A)

(B)

(C)

(D)

(E) (outer)



OD-X .038 +/- .001 height 1.25 +/- .001

= D1

OD-Y .038 +/- .001 width 1.25 +/- .001

W1 1.25 +/- .001

ID1 .032 +/- .001 height 1.25 +/- .001

W2 1.25 +/- .001

ID2 .032 +/- .001 width 1.25 +/- .001

W3 1.25 +/- .001

R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
- (See R&D Production Control to Schedule Requests)

Requester : Steve Schable Ext. # : 53948
 Project Name : Extrusion Dept. # : 1434
 Project # : Net .014 Product : Prox shaft DOE

Date : 6/8/94

Reference Document (SA, WC, or Previous Extr. #)

Material : WRG or ACS RUL ACS or WRG lot 1

100 Victrex PEEK 316

Quantity : 1 Reel(s) with 1000 Feet each.Or 1 Cut Pieces 1000 Cm. 1000 MmResolution Line : 1000 Mm 1000 Mm 1000 MmTooling (if known) : Die : .094 To be designedMandrel : .072 Y or NScrew : PE 4770-3 Y or N

Dimensions (as in all tool req's) :

% Conc. : 0
Ovality : 0Special Instructions : Screw speed = 2.0 rpmAir gap = 1.0"Die Temp = 715°F

Please Illustrate Tubing Dimensions Below
 (Circle Appropriate Letter and Fill in All that Apply)

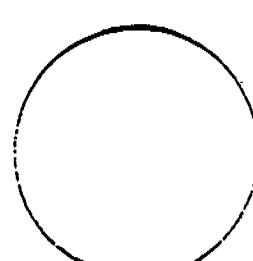
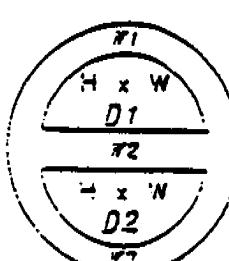
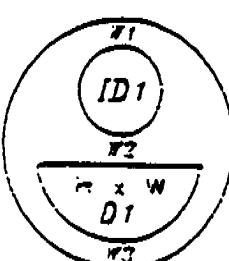
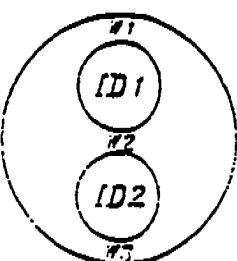
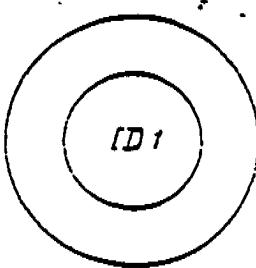
(A)

(B)

(C)

(D)

(E) (outer)

OD-X .038 +/- .001Height 1 +/- 0W1 1 +/- 0OD-Y .038 +/- .001Width 1 +/- 0W2 1 +/- 0ID1 .032 +/- .001Height 1 +/- 0W3 1 +/- 0ID2 1 +/- 0Width 1 +/- 0

R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
(See Prod. Production Control to Schedule Controls)

Requester : Steve Schable Ext. # : 53948
Print Name : Extrusion Dept. # : 1434

Project : Next .014 Product : Prox shaft DOE
Project # : 1315

Reference Document Previous (SA, NC, etc.)

% : Material : MFG or ACS MIL ACS or MFG int'l
100 : Victek PEEK 3816

Quantity : 1 Reel(s) with 1000 feet each.

or Cut Pieces

Resolution : 1000 " in 10' guid

Length (in mm) : 199 to be designed
Mandrel : .166 Y or N
Screw : PE 4770-3 Y or N

Dimensions (in mm) : % Conc. :
% Ovally :

Special Instructions : Screw speed = 2.0 rpm

Avg sp = 1.0 "

Die Temp = 675°F

Please Illustrate Tubing Dimensions Below
(Circle Appropriate Letter and Fill in All that Apply)

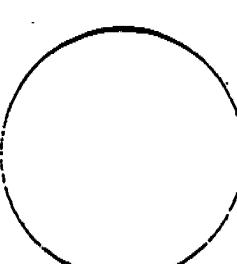
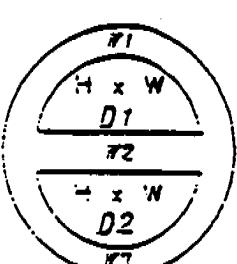
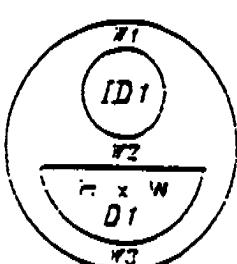
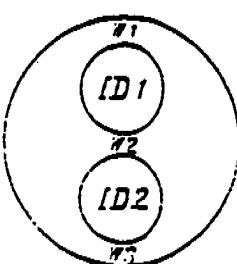
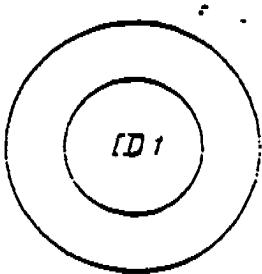
A

B

C

D

E (outer)



OD-X .038 +/- .001

Height 1 +/- 0

OD-Y .038 +/- .001

Height 0 +/- 0

W1 0 +/- 0

ID1 .032 +/- .001

Height 0 +/- 0

W2 0 +/- 0

ID2 0 +/- 0

Height 0 +/- 0

W3 0 +/- 0

R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
- {See Prod. Production Control to Schedule Clinicals}

Requester : Steve ScheibleExt. # : 53948Dept. # : 1434Project : Next .014Product : Pro shaft DOEProject # : 1315Date : 6/8/94

Reference Document Previous Ext. #

% Material : 100 Victek PEEK 3816Wg or ACS # : 1

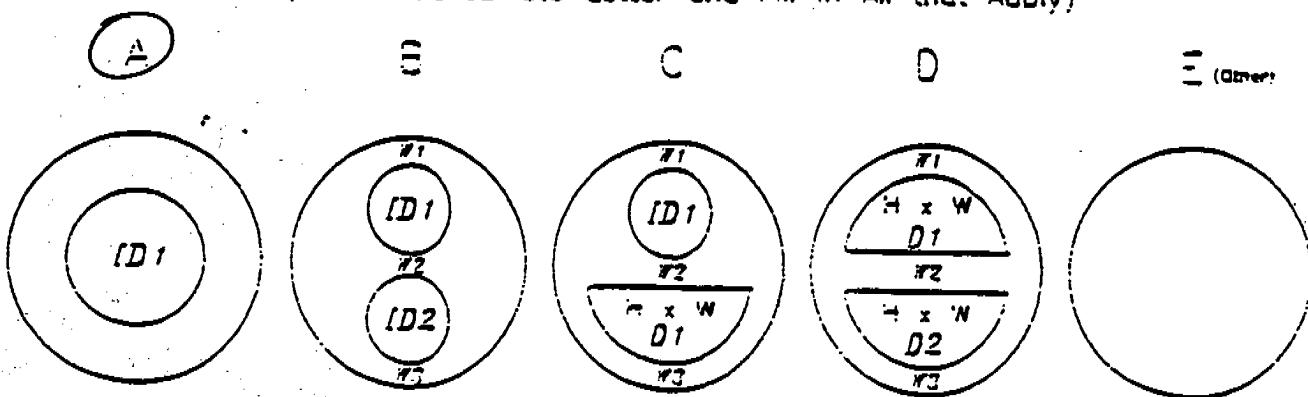
ACG or Wg lot #

100

Quantity : 1 Reel(s) with 1000 Feet each.
 or 1 Cut Pieces 1000 Cm. $\frac{1}{2} \times \frac{1}{2}$

Resolution : None Miles {1000" = 10' right}Drawing (if known) : None .094 Y or NMandrel : .072 Y or NScrew : PE 4770-3 Y or NDimensions (in in not mils) : % Conc. : 0.001Special Instructions : Screw speed = 2.0 rpmAir gap = 60°Dia Temp = 715°F

Please Illustrate Tubing Dimensions Below
 (Circle Appropriate Letter and Fill in All that Apply)

OD-X .038 +/- .001 height 1/2 1/2= D1OD-Y .038 +/- .001 height 1/2 1/2W1 1/2 1/2= D2W2 1/2 1/2ID1 .032 +/- .001 height 1/2 1/2W3 1/2 1/2ID2 +/- height 1/2 1/2= D3

R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
- (See Production Control to Schedule Clinicals)

Date : 6/8/94

Requester : Steve Scheible Ext.# : 53948
 Dept. Name : Extrusion Dept.# : 1434
 Project : Next .014 Product : Prok shaft D0E
 Project # : 1315

Reference Document Previous (SA, NC, or Extr. #)

: Material : WRG or ACS RM 1 ACS or WRG lot # 1
 100. Victrex PEEK 381G

Quantity : 1 Reel(s) with 1000 Feet each.or 1 Cut Pieces 1000 in. .010 in. .005 in.Radiation Dose : 1000 Mrads {1000 Mrads to each end for testing}

to be designed

cooling (if required)

Die : .199 Y or NMandrel : .166 Y or NScrew : PE 4770-3 Y or N

Dimensions (in in all that apply): % Conc. : 100
 Overall : 100

Typical Instructions : Screw Speed = 2.0 rpmAir gap = 60"Dx Temp = 675°F

Please Illustrate Tubing Dimensions Below
 (Circle Appropriate Letter and Fill in All that Apply)

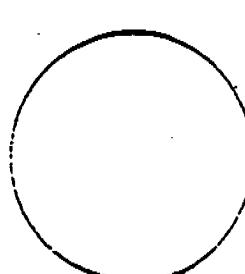
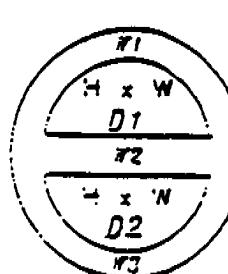
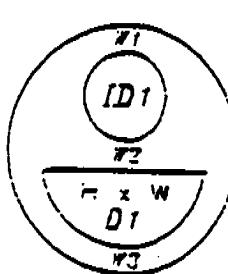
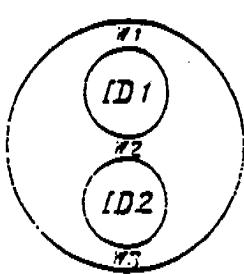
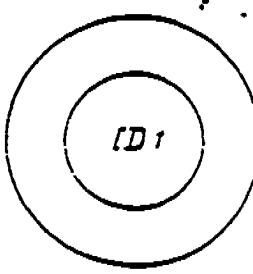
A

B

C

D

E (Other)

OD-X .038 +/- .001 height 1 +/- 0

= D1

W1 1 +/- 0OD-Y .038 +/- .001 height 1 +/- 0

= D2

W2 1 +/- 0ID1 .032 +/- .001 height 1 +/- 0

= D3

W3 1 +/- 0ID2 1 +/- 0 height 1 +/- 0

= D4

ADVANCED CARDIOVASCULAR SYSTEMS
EXTRUSION DATA SHEET

START TIME: EXTRUSION #: 10-594-1 AMOUNT (FEET): 1000
FINISH TIME: DATE: 6/8/94 SIGNATURE/DATE John (6-8-94)

MATERIALS : MATERIAL DESC. LOT# : RM#

PEEK

EXTRUDER 10 PROCESS PERSON T.T9MAS

REQUESTOR S.S.

PRODUCT 1315 SA#

SET-UP PARAMETERS:

MANDREL LGTH (EXT ONLY)	FLUSH	EXPERIMENTAL Y
DIE I.D. .199	OVAL N	PRODUCTION N
MANDREL O.D. .166	ROUND Y	STRAIGHT N
SCREW TYPE PE 4770-3	XHEAD Y	
SCREEN TYPE 20 80 20		
START ID/OD .032/.038		
FINISH ID/OD .032/.038		

PROCESS PARAMETERS

TEMPERATURE SETPOINTS SPEEDS & SETPOINTS PSI & AIR

ZONE 1 560.0 MELT	796.0	SCREW RPM	2.1	HEAD PSI	866.0
ZONE 2 650.0 DIE	1	PSI SET	1305.0	DIE PSI	1315.0
ZONE 3 675.0 DIE	2	EXTR. AMP	9.4	AIR PSI	1 0.2
CLAMP 675.0 DIE	3	PUL SPEED	.58		2 0.7
INLET 675.0 W/B TEMP	0.0	W/B DIST. I INCH			3 0.3
G/PUMP 0.0					4 0.3
PMP OUT 565.0					
XHEAD 0.0					
MATERIAL DRYING TMP. <u>300F</u>	DEWPOINT <u>-51</u>	# OF HRS DRYING	<u>36</u>		

ACTUAL PARAMETER COLLECTED EVERY 10 MINUTES

SETPOINT	ACTUAL 1	ACTUAL 2	ACTUAL 3	ACTUAL 4	ACTUAL 5
G/PUMP PSI					1312
PUMP AMP					0
SCREW RPM					2
EXTRUDER AMP					9
PULLER SPEED					
BARREL 1					844
BARREL 2					0
BARREL 3					0
HEAD PSI					1312
TUBING O.D.					0.0000
AVG.DIA.					0.0000
AVG.STD.DEV.					0.0000

R&D EXTRUSION REQUEST FORM

- NOT TO BE USED FOR CLINICAL RUNS -
- (See other Production Control to Schedule Clinicals)

Date : 6/8/94

Requester : Steve Schable Extr. # : 53948
 Proj. Name : Extrusion Dept. # : 1434
 Project : Neet .014 Product : Prox shaft DOE
 Project # : 1315

Reference Document (SA, NC, or Previous Extr. #)

% Material : WRO or ACS MIL 1 ACS or WRO lot # 1
 100 Victek PEEK 3816

Quantity : 1 Reel(s) with 1000 feet each.or ----- Cut pieces ----- Cm. (in. : -----)Retention time : ----- M.R.O.Ds (to each end for bonding)

Length (in mm) : 116 : .044 to be designed
 Mandrel : .072 Y or N
 Screw : PE 4770-3 Y or N

Dimensions (in mm) : % Conc. : -----
 Overall : -----

Special Instructions : Screw speed = 2.0 rpmAir gap = 1.0"Die Temp = 675°F

Please Illustrate Tubing Dimensions Below
 (Circle Appropriate Letter and Fill in All that Apply)

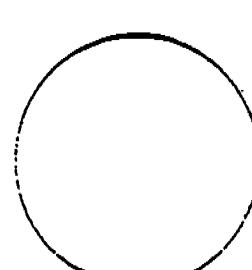
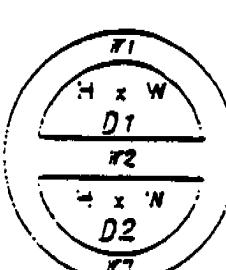
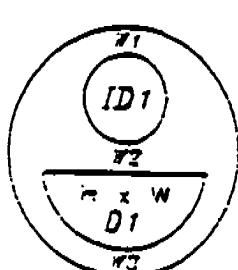
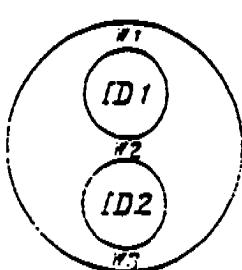
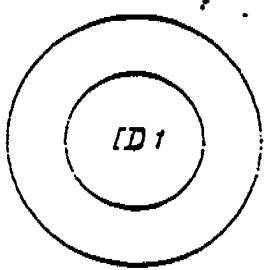
(A)

(B)

(C)

(D)

(E) (outer)

OD-X .038 +/- .001Height ----- +/- -----= D1H1 ----- +/- -----OD-Y .038 +/- .001Height ----- +/- -----ID1 .032 +/- .001Height ----- +/- -----= D2H2 ----- +/- -----ID2 ----- +/- -----Height ----- +/- -----= D3H3 ----- +/- -----